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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,958	11/03/2006	Kristine Fuimaono	32860-001018/US	3084

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HARNESSE, DICKEY & PIERCE, P.L.C.
P.O.BOX 8910
RESTON, VA 20195

EXAMINER

NGUYEN, HIEN NGOC

ART UNIT	PAPER NUMBER
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3777

NOTIFICATION DATE	DELIVERY MODE
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08/04/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

demailroom@hdp.com
siemensgroup@hdp.com
pshaddin@hdp.com

Office Action Summary	Application No. 10/569,958	Applicant(s) FUIMAONO ET AL.	
	Examiner HIEN NGUYEN	Art Unit 3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Drafts, Person's Patent Drawing, Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>05/13/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 5, 8-9, 12, 14 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695), in view of Rose (US 2002/0176608), further in view of Hemler et al. (A System for Multimodality Image Fusion (provided as prior art in the IDS)), Maurincomme et al. (US 2001/0036303) and Webler (US 2007/0055142).

3. Addressing claim 12, Packer discloses a device comprising: at least one input interface for electroanatomical mapping data and 3D image data (see Fig. 1, col. 2, lines 14-60, col. 3, lines 51-67, Packer discloses a device that perform an imaging method therefore the device must have at least one input interface for electroanatomical mapping data and 3D image data); a segmentation module that is capable of segmenting the 3D image data in order to extract a 3D surface image of objects contained within a volume record by way of the 3D image data (see Fig. 2A, col. 6, lines

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14-45 and col.7, lines 7-23); a registration module connected to the segmentation module configured to correlate with the correct position and dimension of the electroanatomical mapping data and the 3D image data representing the 3D surface image, by matching of the 3D surface image from the 3D image data to a 3D surface image from the mapping data in at least one stage of the registration (see Fig. 1, Fig. 8, col. 2, lines 14-60 and col. 9, line 21-col.10, line 36) and a visualization module connected to the registration module superimpose the mapping data and at least the 3D image data representing the 3D surface images on one another in the correct position with the correct dimension and provide these for visualization via a display device (see Fig. 1, Fig. 8, col. 2, lines 14-60, col. 9, line 21-col.10, line 36 and col. 12, lines 28-61). However, Packer does not explicitly disclose surface profile, automatically register (which is automatically matching points, positions and dimensions between two images), the electroanatomical/anatomical map is 3D and surface matching. Rose explicitly discloses surface profile provide images of the surface with fine detail (see claim 9 and [0005-0007]). Hemler explicitly disclose surface matching (see page 335, last paragraph). Maurincomme explicitly discloses automatic registration of 3D images (see abstract, claim 1, [0009] and [0048]). Webler explicitly disclose electroanatomical/anatomical map is 3D (see [0014] and [0147]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packet to include surface profile, surface matching, 3D anatomical map and automatic registration as taught by Rose, Hemler, Maurincomme and Webler because the surface profile,

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surface matching, automatic registration and 3D anatomical map provide extensive detail about the surface, improve image quality, accuracy and efficiency of the device.

Further it would have been obvious to one having ordinary skill in the art at the time of the invention was made to automatically register, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

4. Addressing claim 14, Packer discloses visualization module that is capable of real time visualization of a part of a catheter that is used within a representation of the 3D image data that forms at least the 3D surface images (see col. 2, line 14-60 and col. 13, lines 1-23). Rose discloses surface profile (see claim 9 and [0005-0007]).

5. Addressing claim 1, Packer discloses a method for visually supporting an electrophysiology catheter application in the heart, comprising: visualizing electroanatomical mapping data, provided during the performance of the catheter application, of an area of the heart to be treated (see Fig. 1, col. 2, lines 14-60, col. 11, lines 33-48 and col. 12, lines 28-61); recording 3D image data of the area to be treated with a method of tomographical 3D imaging before the catheter application is carried out (see col. 2, lines 25-37); extracting a 3D surface images of objects in the area to be treated from the 3D image data by segmentation (see col. 5, line 63-col.6, line 48);

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the visualized electroanatomical mapping data and 3D image data representing at least the 3D surface image being registered, with correct position and dimension, by correlating the electroanatomical mapping data and 3D image data representing the 3D surface image by surface matching, in at least one stage of registration, the 3D surface image from the 3D image data to a 3D surface image from the mapping data (see Fig. 1, Fig. 8, col. 2, lines 14-60 and col. 9, line 21-col.10, line 36 and col. 12, lines 28-61). However, Packer does not explicitly disclose surface profile, automatically register (which is automatically matching points, positions and dimensions between two images), the electroanatomical/anatomical map is 3D and surface matching. Rose explicitly discloses surface profile provide images of the surface with fine detail (see claim 9 and [0005-0007]). Hemler explicitly disclose surface matching (see page 335, last paragraph). Maurincomme explicitly discloses automatic registration of 3D images (see abstract, claim 1, [0009] and [0048]). Webler explicitly disclose electroanatomical/anatomical map is 3D (see [0014] and [0147]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packet to include surface profile, surface matching, 3D anatomical map and automatic registration as taught by Rose, Hemler, Maurincomme and Webler because the surface profile, surface matching, automatic registration and 3D anatomical map provide extensive detail about the surface, improve image quality, accuracy and efficiency of the device.

Further it would have been obvious to one having ordinary skill in the art at the time of the invention was made to automatically register, since it has been held that

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broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

6. Addressing claims 19 and 22, a method and device for visually supporting an electrophysiology catheter application in the heart, comprising: recording 3D image data of an area of the heart to be treated with a method of tomographical 3D imaging, before electroanatomical mapping data is provided during the performance of the catheter application (see col. 2, lines 25-37); extracting a 3D surface images of objects in the area to be treated from the 3D image data by segmentation (see col. 5, line 63-col.6, line 48); registering, with correct position and dimension, by correlating the electroanatomical mapping data and 3D image data representing the 3D surface image by matching, in at least one stage of registration, the 3D surface image from the 3D image data to a 3D surface image from the mapping data (see Fig. 1, Fig. 8, col. 2, lines 14-60 and col. 9, line 21-col.10, line 36); and displaying mapping data and the 3D image data representing the 3D surface image superimposed on one another in correct dimension and position (see Fig. 1, Fig. 8, col. 2, lines 14-60 and col. 9, line 21-col.10, line 36). However, Packer does not explicitly disclose surface profile, automatically register (which is automatically matching points, positions and dimensions between two images), the electroanatomical/anatomical map is 3D and surface matching. Rose explicitly discloses surface profile provide images of the surface with fine detail (see claim 9 and [0005-0007]). Hemler explicitly disclose surface matching (see page 335,

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last paragraph). Maurincomme explicitly discloses automatic registration of 3D images (see abstract, claim 1, [0009] and [0048]). Webler explicitly disclose electroanatomical/anatomical map is 3D (see [0014] and [0147]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packet to include surface profile, surface matching, 3D anatomical map and automatic registration as taught by Rose, Hemler, Maurincomme and Webler because the surface profile, surface matching, automatic registration and 3D anatomical map provide extensive detail about the surface, improve image quality, accuracy and efficiency of the device.

Further it would have been obvious to one having ordinary skill in the art at the time of the invention was made to automatically register, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

7. Addressing claims 2-3, 5, 8-9, 20-21 and 23-24 wherein the 3D image data of the area to be treated are recorded with a method of at least one of X-ray computer tomography and magnetic resonance tomography (see col. 1, lines 15-35 and col. 3, lines 51-67); wherein the 3D image data of the area to be treated are recorded by use of a 3D ultrasound (see col. 1, lines 15-35 and col. 3, lines 51-67); the 3D image data are visualized via a volume rendering technique (see col. 6, line 1-13); wherein a registration is effected between a catheter used during the catheter application and the

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3D image data and at least a part of the catheter is visualized in real time in the representation of the 3D image data representing at least the 3D surface images (see col. 2, lines 53-60, col. 3, lines 25-38 and Figs. 3-7); visualize catheter without superimposition of the mapping data from time to time (see col. 2, lines 53-60).

8. Claims 4, 13, 18 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695), in view of Rose (US 2002/0176608), further in view of Hemler et al. (A System for Multimodality Image Fusion (provided as prior art in the IDS)), Maurincomme et al. (US 2001/0036303), Webler (US 2007/0055142) and Williams et al. (DE 19953308-A1 (provided as prior art in the IDS)).

9. Addressing claim 4, Packer does not disclose registering with the correct position and dimension by automatically correlate using distinct anatomical points and artificial marker. Hemler discloses register by correlate the correct position and the correct dimension using distinct anatomical points as an effective way to ensure the images on display are in correct position and dimension (see page 337, line 7- page 338, line 32). Williams discloses correlate the correct position and the correct dimension using artificial marker as an effective way to ensure the images on display are in correct position and dimension (see abstract). Maurincomme discloses multiple stages of registration (see [0054] and Fig. 2). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packer's system to correlate the correct position and the correct dimension using distinct anatomical points and artificial marker

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taught by Hemler and Williams because using multiple stages, distinct anatomical points and artificial marker are effective way to ensure the images display are in correct position, dimension and improve precision.

10. Addressing claims 13 and 25-26, Packer does not disclose correlate the correct position and the correct dimension using distinct anatomical points and artificial marker. Hemler discloses correlate the correct position and the correct dimension using distinct anatomical points as an effective way to ensure the images on display are in correct position and dimension (see page 337, line 7- page 338, line 32). Williams discloses correlate the correct position and the correct dimension using artificial marker as an effective way to ensure the images on display are in correct position and dimension (see abstract). Maurincomme discloses multiple stages of registration (see [0054] and Fig. 2). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packer's system to correlate the correct position and the correct dimension using distinct anatomical points and artificial marker taught by Hemler and Williams because using multiple stages, distinct anatomical points and artificial marker are effective way to ensure the images display are in correct position, dimension and improve precision.

11. Addressing claim 18, Packer discloses visualization module is constructed for visualizing a part of a catheter used within a representation of the 3D image data, forming at least the 3D surface image, in real time (see col. 2, line 14-60).

12. Claims 10-11 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695), in view of Rose (US 2002/0176608), further in view of Hemler et al. (A System for Multimodality Image Fusion (provided as prior art in the IDS)), Maurincomme et al. (US 2001/0036303), Webler (US 2007/0055142) and Solomon et al. (US 2003/0018251).

13. Addressing claims 10-11 and 17, Packer, Rose, Hemler, Maurincomme and Webler do not disclose an instantaneous distance of a catheter tip from a predeterminable picture element of the 3D image data and the distance is represented by color coding of the visualization of the catheter. Solomon discloses an instantaneous distance of a catheter tip from a predeterminable picture element of the 3D image data and the distance is represented by color coding of the visualization of the catheter (see [0056-0058]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packer's method to have an instantaneous distance of a catheter tip from a predeterminable picture element of the 3D image data and the distance is represented by color coding of the visualization of the catheter as taught by Solomon because the coded representation provide a better visualization for the operator and the operator can easily determine the distance by looking at the color code.

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14. Addressing claims 15-16, Packer, Rose, Hemler, Maurincomme and Webler do not disclose a calculation module to calculate an instantaneous distance of a catheter tip from a predeterminable picture element of the 3D image data. Packer also does not disclose the visualization module for the coded representation of the calculated distance in real time. Solomon discloses a system that included a calculation module to calculate an instantaneous distance of a catheter tip from a predeterminable picture element of the 3D image data, the visualization module and a method step for the coded representation of the calculated distance in real time for better visualization for the operator (see [0056-0058]). The calculated module is inside the system. The system has to have a calculation module in order to make the calculation. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packer's system with a calculation module to calculate an instantaneous distance of a catheter tip from a predeterminable picture element of the 3D image data, the visualization module being constructed for the coded representation of the calculated distance in real time taught by Solomon because the coded representation provide a better visualization for the operator and the operator can easily determine the distance by looking at the color code.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695), in view of Rose (US 2002/0176608) further in view of Hemler et al. (A System for Multimodality Image Fusion (provided as prior art in the IDS)),

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Maurincomme et al. (US 2001/0036303), Webler (US 2007/0055142) and further in view of Massaro et al. (2002/0087329).

16. Addressing claim 6, Packer, Rose, Hemler, Maurincomme and Webler do not disclose visualized image data on a polygonal grid. Massaro discloses visualize image on a polygonal grid for easily matching location and distance (see claim 58). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packer's method to visualized image data on a polygonal grid taught by Massaro because with a polygonal grid the viewer can easily match location and determine distance.

17. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695), in view of Rose (US 2002/0176608), further in view of Hemler et al. (A System for Multimodality Image Fusion (provided as prior art in the IDS)), Maurincomme et al. (US 2001/0036303), Webler (US 2007/0055142), Shoji et al. (US 6,572,476) and Chiu et al. (US 2004/0233217).

18. Addressing claim 7, Packer, Rose, Hemler, Maurincomme and Webler do not disclose adjustable transparency and adjustable blending factor. Shoji discloses adjustable transparency to make the image more or less visible (see col. 9, lines 1-22). Chiu discloses adjustable blending factor to control the visibility of the output image (see [0007-0008]). It would have been obvious to one of ordinary skill in the art to modify

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Packer's method with adjustable transparency and adjustable blending factor taught by Shoji and Chiu because adjustable transparency and adjustable blending factor allow the operator to adjust the level of visibility of the images.

Response to Arguments

Applicant's arguments filed 07/07/2011 have been fully considered but they are not persuasive. Applicant argues the references alone or in combination do not disclose automatic registration of electroanatomical 3D mapping data and 3D image data representing the 3D surface profile. Applicant argument is not persuasive because Packer disclose registration of electroanatomical mapping data and image data (see Fig. 1, 2A, col. 2, lines 14-60, col. 3, lines 51-67, col. 6, lines 14-45 and col.7, lines 7-23). Packer does not disclose automatic registration, electroanatomical 3D mapping data and surface profile. Rose explicitly discloses surface profile provide images of the surface with fine detail (see claim 9 and [0005-0007]). Maurincomme explicitly discloses automatic registration of 3D images (see abstract, claim 1, [0009] and [0048]). Webler explicitly disclose electroanatomical/anatomical map is 3D (see [0014] and [0147], the 3D diagnostic/anatomical maps is the 3D electroanatomical mapping data). Therefore the combination of references discloses the claim limitation. Both Packer and Webler use the electro on the catheter to map the heart and that is electroanatomical mapping data.

Applicant argues Rose reference is about surface road therefore it would not have been obvious to one of ordinary skill in the art at the time of the invention to combine Rose with Packer. Applicant argues Rose reference is not about medical imaging and Rose does not disclose visualizing electroanatomical 3D mapping data. Applicant argues examiner used hindsight in the combination and the art are non-analogous. Applicant's argument is not persuasive because Rose extracts surface profile from images of roads. The references are from the field of imaging. Examiner only relied on Rose to disclose surface profile. Packer already discloses visualizing electroanatomical mapping data. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In response to applicant's argument that Rose is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the analogous art is imaging. It would have been obvious to one of ordinary skill in the art at the time of the invention to use imaging techniques

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from roads, architecture, web/graphic design, movies, etc. for medical imaging because this only require ordinary skill in the art and these technique would improve medical imaging.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HIEN NGUYEN whose telephone number is (571)270-7031. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Chen can be reached on (571) 272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3777

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3777